Subpart D—Testing Procedures

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 60 FR 52507, Oct. 6, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 355.1 Scope.

(a) An over-the-counter anticaries drug product in a form suitable for topical administration to the teeth is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in §330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 355.3 Definitions.

As used in this part:

(a) *Abrasive.* Solid materials that are added to dentifrices to facilitate mechanical removal of dental plaque, debris, and stain from tooth surfaces.

(b) *Anhydrous glycerin.* An ingredient that may be prepared by heating glycerin U.S.P. at 150 –C for 2 hours to drive off the moisture content.

(c) *Anticaries drug.* A drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries).

(d) *Dental caries.* A disease of calcified tissues of teeth characterized by demineralization of the inorganic portion and destruction of the organic matrix.

(e) *Dentifrice.* An abrasive-containing dosage form (gel, paste, or powder) for delivering an anticaries drug to the teeth.

(f) *Fluoride.* The inorganic form of the chemical element fluorine in combination with other elements.

(g) *Fluoride ion.* The negatively charged atom of the chemical element fluorine.

(h) *Fluoride supplement.* A special treatment rinse dosage form that is intended to be swallowed, and is promoted to health professionals for use in areas where the water supply contains 0 to 0.7 parts per million (ppm) fluoride ion.

(i) *Preventive treatment gel.* A dosage form for delivering an anticaries drug to the teeth. Preventive treatment gels are formulated in an anhydrous glycerin base with suitable thickening agents included to adjust viscosity. Preventive treatment gels do not contain abrasives.

(j) *Treatment rinse.* A liquid dosage form for delivering an anticaries drug to the teeth.

(k) *Treatment rinse concentrated solution.* A fluoride treatment rinse in a concentrated form to be mixed with water before using to result in the appropriate fluoride concentration specified in the monograph.

(l) *Treatment rinse effervescent tablets.* A fluoride treatment rinse prepared by adding an effervescent tablet (a concentrated solid dosage form) to water before using to result in the appropriate fluoride concentration specified in the monograph.

(m) *Treatment rinse powder.* A fluoride treatment rinse prepared by adding the powder (a concentrated solid dosage form) to water before using to result in the appropriate fluoride concentration specified in the monograph.

[60 FR 52507, Oct. 6, 1995, as amended at 61 FR 52286, Oct. 7, 1996]

Subpart B—Active Ingredients

§ 355.10 Anticaries active ingredients.

The active ingredient of the product consists of any of the following when used in the concentration and dosage form established for each ingredient:

(a) *Sodium fluoride*—(1) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a gel or paste dosage form.* Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration ≥ 650 parts per million (ppm).

(2) *Dentifrices containing 850 to 1,150 ppm theoretical total fluorine in a powdered dosage form.* Sodium fluoride 0.188 to 0.254 percent with an available fluoride ion concentration of ≥ 850 ppm for products containing the abrasive sodium bicarbonate and a poured-bulk density of 1.0 to 1.2 grams per milliliter.

(3) *Treatment rinses.* (i) An aqueous solution of acidulated phosphate fluoride